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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,112	03/05/2007	Craig A. Judy	0765-005US1	1150

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EXAMINER	
PURDY, KYLE A	
ART UNIT	**PAPER NUMBER**
1611	

MAIL DATE	DELIVERY MODE
12/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/598,112	**Applicant(s)** JUDY ET AL.	
	Examiner Kyle Purdy	**Art Unit** 1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 December 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-14*.
   Claim(s) withdrawn from consideration: *13-27*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Kyle Purdy/
Examiner, Art Unit 1611

/David J Blanchard/
Primary Examiner, Art Unit 1643

Continuation of 11. does NOT place the application in condition for allowance because: Applicants arguments filed 12/01/2008 regarding the rejection of claims 1-5 and 10 made by the Examiner under 35 USC 102(b) over Dandiker et al. (US 5425950) have been fully considered but they are not found persuasive.
Applicants arguments filed 12/01/2008 regarding the rejection of claims 1-5 and 10-14 made by the Examiner under 35 USC 103(a) over Dandiker et al. (US 5425950) in view of Lerner et al. (US 2004/0052843) have been fully considered but they are not found persuasive.
Applicants arguments filed 12/01/2008 regarding the rejection of claims 1 and 5-9 made by the Examiner under 35 USC 103(a) over Dandiker et al. (US 5425950) in view of Liberman et al. (Pharma. Dosage Forms, 1990) have been fully considered but they are not found persuasive.
In regards to the 102(b) and 103(a) rejections, Applicant asserts the following:
A) Example 10 of Dandiker cited by the Examiner does not teach a rapid release mantle, free of sumatriptan;
B) Danidker does not teach microcrystalline cellulose as being used as both the filler and disintegrant;
C) Lieberman does not teach or suggest a rapid release layer; and
D) The tablets disclosed by Lerner do not disclose the tablet as being completely coated by the coating layer.
In response to assertion A, this argument is not found persuasive. As was noted in the final office action mailed on 09/30/2008, Dandiker teaches a composition with the following structure:
I) a core containing sumatriptan;
II) a coating free of sumatriptan; and
III) a coating containing sumatriptan.
Applicant suggests that this composition does not anticipate the instantly claims because layer II does not have immediate release properties. The Examiner respectfully disagrees. First of all, Applicant fails to limit the claim in a sufficient way so as to delineate what is encompassed by 'rapid' release. Applicant acknowledges that the layer II is suitable for immediate release in certain environments, but not others. See page 13 of response. Albeit true that there may be some kind intermediate time between ingestion and release of drug, upon arriving in the preferred environment, the dosage form will rapidly disintegrate and the drug will be rapidly released. Claim 1 provides no such direction as to what properties/environments are capable of providing a rapid release property, thus in a broad interpretation of the claim, rapid release in the intestine (or anywhere else, for that matter) of a subject is sufficient to anticipate the claim. The fact that rapid release doesn't occur in the stomach or any other environment which Applicant desires does not mitigate the anticipatory nature of the reference, because the end result is a rapid release of drug. If Applicant wishes to claim a rapid oral, stomach, upper intestine or lower intestine release composition, then Applicant should claim is as such.
In response to assertion B, the Examiner has erred. The Examiner agrees that microcrystalline cellulose is not serving as both the filler and the disintegrant. Rather, the microcrystalline is serving as the disintegrant and the lactose is serving as the filler.
In response to assertion C, it is agreed that Lieberman does not teach or suggest a rapid release layer. Dandiker is relied upon though to teach this particular property. Lieberman is relied upon to show that absorbents are commonly used in the field of tablet manufacturing. Absorbents especially because they prevent the absorption of moisture during the granulation process, thereby providing a dosage form with smooth and non-scratched surfaces. Moreover, Applicant suggests that because Lieberman mentions prolonged release dosage forms (prior to section discussing tabletting manufacturing), it would have been non-obvious to incorporate an absorbent into the composition of Dandiker. This argument is not found persuasive either because the primary teaching to Dandiker is relied upon for teaching a rapid release dosage form. Lieberman is relied upon to show that absorbents are commonly added to tablet formulations, regardless of the type, to enhance the manufacturing of pharmaceutical tablets and ensure the final product is safe and consumable. Absent any evidence that absorbents alter the rate of drug release, it is the position of the Examiner that including absorbents in any type of tabletted dosage form would be obivous to one of ordinary skill in the art.
With respect to assertion D, it is acknowledged that Lerner teaches a tablet wherein the coating layer does not entirely coat the drug containing core. However, this point is moot because the primary teaching to Dandiker teaches coating the drug containing core entirely. Lerner is relied because it teaches a sumatriptan composition comprising a core wherein 80% of the core is dissolved within 30 minutes and the coating of the core is entirely dissolved within an hour. Lerner is relied upon to show Applicants properties are obvious and are commonly subjected to optimization. The rate of disintegration of core and coating structures are routinely subjected to optimization. It is well known in the art that if one desired to adjust the rate of release for a tablets core and/or coating, adjusting the amount of disintegrant, for one, would result in altering the rate of disintegration. Such an undertaking would be favorable to deliver the drug immediately to relive the subjects migraine rather require the subject to wait for relief.